

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

§

In re application of: Walker et al.

Serial No. 09/668,831

Filed: September 22, 2000

For: CORDLESS SURGICAL HANDPIECE WITH DISPOSABLE BATTERY AND

METHOD

Attorney Docket No. 31849.24 / P-9736.01

Customer No. 27683

Group Art Unit: 3731

Examiner: D. Jacob Davis

TRANSMITTAL

Mail Stop: APPEAL BRIEFS-PATENTS Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following regarding the above-identified patent application:

- 1. Brief of Appellant in triplicate;
- 2. Check in the amount of \$330.00;
- 3. Transmittal sheet in duplicate; and
- 3. Return postcard.

The Commissioner is hereby authorized to charge payment of any further fees associated with any of the papers submitted herewith or to credit any overpayment to Deposit Account No. 08-1394.

Respectfully submitted,

David M. O'Dell

Registration No. 42,044

Dated: 8-30-04

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

§ § §

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Serial Number: 09/668,831

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For: CORDLESS SURGICA

CORDLESS SURGICAL
HANDPIECE WITH
DISPOSABLE BATTERY

AND METHOD

BRIEF OF APPELLANT

Mail Stop: APPEAL BRIEFS-PATENT Commissioner For Patents P. O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Brief is submitted in connection with an appeal from the final rejection of the Examiner dated May 18, 2004, finally rejecting claims 1-12 and 29-32, all of the pending claims in this application. Two additional copies of this Brief are submitted herewith.

REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc. (d/b/a Medtronic Midas Rex), a Delaware company having a principal place of business at LC 340, 710 Medtronic Parkway, Minneapolis, Minnesota 55432, United States of America.

RELATED APPEALS AND INTERFERENCES

There are no related appeals and no related interferences regarding the above-identified patent application.

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STATUS OF CLAIMS

The present application was filed on September 22, 2000 and is a Continuation of US Application Serial No. 09/349,643, filed on July 8, 1999 (now patent no. 6,126,670) which claims benefit of Provisional Application Serial No. 60/112,678, filed on December 16, 1998. The present application originally included twenty eight (28) claims, eleven (11) of which (claims 1, 3-5, 11, 13, 17, 21, 22, 25, and 27) were independent.

Pending claims (1-12 and 21) were rejected in a first Office Action mailed September 27, 2002. Claims 13-20 were withdrawn from consideration.

In response to the first Office Action, Applicants filed an "Amendment" on December 10, 2002. The Amendment cancelled claim 21 and amended claim 1.

Claims 1-12 were rejected and claims 22-28 were withdrawn from consideration in a final Office Action mailed February 6, 2003.

In response to the final Office Action, Applicants filed a "Response to Final Rejection" on March 17, 2003. The Response to Final Rejection proposed claim amendments to claims 1, 4 and 5 differentiating the claimed invention from the prior art.

An Advisory Action was mailed on April 8, 2003. In a telephone interview on April 23, 2003, the Examiner agreed to withdraw the finality of the February 6, 2003 office action. Consequently, a "Request to Remove the Finality of Office Action & Response to Office Action" was filed by the Applicants on April 25, 2003.

In a non-final Office Action mailed May 16, 2003, claims 1-12 were again rejected. A "Request for Reconsideration" was filed on August 15, 2003, adding claim 29. Claims 1-12 and 29 were then rejected in a non-final Office Action mailed November 21, 2003.

Another telephone interview was held on February 11, 2004, and in response, the Applicants filed a "Request for Reconsideration" on February 18, 2004, adding claims 30-32 and amending claims 1, 3-5, 11, and 29. A final Office Action ("Final Office Action") rejecting pending claims 1-12 and 29-32 was mailed on May 18, 2004.

The status of the claims as set out in the Final Office Action was and is as follows:

claims allowed: none;

claims objected to: none;

claims rejected: 1-12 and 29-32;

claims cancelled: 21;

claims withdrawn form consideration: 13-20 and 22-28.

Claims 1-12 and 29-32 are set forth in Appendix A attached hereto.

STATUS OF AMENDMENTS AFTER FINAL REJECTION

No response or amendments have been filed in response to the final Office Action of May 18, 2004.

SUMMARY OF THE INVENTION

The present invention, in one embodiment as now set forth in independent claim 1, relates to a surgical instrument comprising a handpiece (Fig. 1a; Figs. 3-6; Fig. 8; Fig. 9; Fig. 13; page 9, lines 12-14) having a tool supporting end (Fig. 1a; Fig. 3; Fig. 13; page 9, lines 12-18) and a battery receiving end (Fig. 1a; Fig. 3; Fig. 13; page 9, lines 12-18; page 10, lines 23-25). The battery receiving end has a first set of substantially concentrically arranged electrical contacts (Fig. 3; Fig. 6; Fig. 8; Fig. 9; page 10, line 26- page 11, line 1) and first and second opposing flanges (Fig. 3; Fig. 6; page 11, lines 10-16; page 12, line 21 – page 13, line 4) substantially perpendicular to and opposing a longitudinal axis of the handpiece. The first and second opposing flanges are separated by first and second gaps of substantially different widths opposing the longitudinal axis (Fig. 3; Fig. 6; page 12, line 21 – page 13, line 4) The surgical instrument also includes a sterile package (Fig. 2; page 10, lines 9-22) comprising a single surgical use, disposable battery pack (Figs 1a- 5; Fig. 7-10; Fig. 12; Fig. 13; page 9, lines 12-18) having an attachment end (Fig. 3; page 11, lines 10-16). The attachment end has a second set of substantially concentrically arranged electrical contacts (Fig. 3; Fig. 7; page 11, lines 1-9) and third and fourth flanges opposing the handpiece longitudinal axis (Fig. 3; Fig. 7; page 13, lines 5-17). The third and fourth flanges are substantially parallel to and slidably engaged with the first and second opposing flanges. The third and fourth flanges are also configured to pass through a

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corresponding one of the first and second gaps in a single, predetermined relative position (page 13, lines 5-17). Rotation of the battery pack relative to the handpiece causes the two sets of contacts to become lockingly and conductively interengaged (Fig. 3-5; page 14, lines 1-10). Rotation of the battery pack relative to the handpiece also causes the third and fourth flanges to become engaged with a corresponding one of the first and second flanges (page 13, lines 5-17).

Another embodiment of the present invention, as now set forth in claim 5, relates to a surgical instrument for performing a cutting, shaping, or drilling operation on live human bone or hard tissue (page 6, lines 15-19). The surgical instrument in this embodiment includes a handpiece (Fig. 1a; Figs. 3-6; Fig. 8; Fig. 9; Fig. 13; page 9, lines 12-14) having a battery receiving end (Fig. 1a; Fig. 3; Fig. 13; page 9, lines 12-18; page 10, lines 23-25) with an alignment post (Fig. 3, Fig. 6, Fig. 8, Fig. 9, page 10, lines 23-25) extending therefrom. The handpiece also has a tool supporting end (Fig. 1a; Fig. 3; Fig. 13; page 9, lines 12-18) for supporting a tool for performing a cutting, shaping, or drilling operation on live human bone or hard tissue. The surgical instrument also includes a sterile package (Fig. 2; page 10, lines 9-22) containing a single use, disposable battery pack (Figs 1a- 5; Fig. 7-10; Fig. 12; Fig. 13; page 9, lines 12-18) which has an attachment end (Fig. 3; page 11, lines 10-16) with a central opening (Fig. 3, Fig. 7-9, page 11, lines 1-9) therein. The central opening in the single use, disposable battery pack is adapted to insertably receive the alignment post so as to establish a mutual alignment axis of handpiece and battery pack (Fig. 8; page 11, lines 22-25; page 13, lines 18-22). The battery receiving end of the handpiece and the attachment end of the single use, disposable battery pack have flat end surfaces for abutting engagement while yet allowing relative rotation of the battery pack relative to the handpiece (page 11, lines 10-16). The battery receiving end of the handpiece and the attachment end of the single use, disposable battery pack have mating sets of electrical contact elements, each set being arranged generally concentric to the mutual alignment axis (Fig. 3; Fig. 6; Fig. 7; page 11, lines 17-21). Upon the insertion of the alignment post of the handpiece into the opening of the battery pack, the sets of mating contacts become lockingly and conductively interengaged in response to rotation of the battery pack relative to the handpiece (Fig. 8; Fig. 9; page 11, lines 21-25).

Another embodiment of the present invention, as now set forth in claim 11, relates to a

surgical instrument for performing a surgical drilling procedure on bone or hard tissue (page 6, lines 15-19). The surgical instrument in this embodiment includes a handpiece (Fig. 1a; Figs. 3-6; Fig. 8; Fig. 9; Fig. 13; page 9, lines 12-14) having a rotary driven drilling member (page 6, lines 15-19; page 8, lines 20-25; page 9, lines 19-26); supported by a tool supporting end (Fig. 1a; Fig. 3; Fig. 13; page 9, lines 12-18) and a battery receiving end (Fig. 1a; Fig. 3; Fig. 13; page 9, lines 12-18; page 10, lines 23-25) with an alignment post (Fig. 3, Fig. 6, Fig. 8, Fig. 9, page 10, lines 23-25) extending therefrom. The battery receiving end of the handpiece also has a set of electrical contact elements arranged in generally concentric relation to the alignment post (Fig. 3; Fig. 6; Fig. 8; Fig. 9; page 10, line 26-page 11, line 1). The surgical instrument also includes a disposable battery (Figs 1a- 5; Fig. 7-10; Fig. 12; Fig. 13; page 9, lines 12-18) having an attachment end (Fig. 3; page 11, lines 10-16) with a central opening therein (Fig. 3, Fig. 7-9, page 11, lines 1-9). The disposable battery also includes a set of mating electrical contact elements arranged in a generally circular configuration concentric to the central opening therein (Fig. 3; Fig. 7; page 11, lines 1-9). The central opening in the disposable battery receives the alignment post of the handpiece in a partially inserted position so as to establish a pre-attachment alignment (Fig. 8; page 11, lines 22-25; page 13, lines 18-22). The sets of mating contacts come into a mutually concentric relation in response to a further insertion of the alignment post into the central opening (page 11, lines 17-25). The sets of contacts then become lockingly and conductively interengaged upon rotation of the battery pack relative to the handpiece (Fig. 8; Fig. 9; page 11, lines 21-25).

Another embodiment of the present invention, as now set forth in claim 29, relates to a surgical instrument for removing live human bone or hard tissue (page 6, lines 15-19). The instrument comprises a handpiece (Fig. 1a; Figs. 3-6; Fig. 8; Fig. 9; Fig. 13; page 9, lines 12-14) which includes a first end supporting a rotary driven tool configured to remove live human bone or hard tissue by rotation of a cutting member in response to rotary drive means within the handpiece (page 6, lines 15-19; page 8, lines 20-25; page 9, lines 19 – page 10, line 1). The handpiece also includes a second end which has an alignment post extending therefrom and defining a handpiece longitudinal axis (Fig. 3, Fig. 6, Fig. 8, Fig. 9, page 10, lines 23-25) and a plurality of handpiece electrical contacts arranged concentric to the handpiece longitudinal axis (Fig. 3; Fig. 6; Fig. 8; Fig. 9; page 10, line 26- page 11, line 1). The instrument further

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comprises a-sterile, disposable battery pack which includes lithium/manganese dioxide batteries (Figs 1a- 5; Fig. 7-10; Fig. 12; Fig. 13; page 9, lines 12-18; page 10, lines 9-22) and an attachment end (Fig. 3; page 11, lines 10-16) secured to the handpiece second end by a rotating movement of the disposable battery pack relative to the handpiece (Fig. 8; Fig. 9; page 11, lines 21-25). The attachment end has an opening defining a battery pack longitudinal axis (Fig. 3, Fig. 7-9, page 11, lines 1-9) and a plurality of battery pack electrical contacts arranged concentric to the battery pack longitudinal axis (Fig. 3; Fig. 7; page 11, lines 1-9). The attachment end opening receives the handpiece alignment post to establish a mutual alignment axis between the handpiece longitudinal axis and the battery pack longitudinal axis (Fig. 8; page 11, lines 22-25; page 13, lines 18-22). The pluralities of the handpiece and battery pack contacts are mating pluralities of contacts configured to be lockingly and conductively interengaged by the rotating movement (Fig. 8; Fig. 9; page 11, lines 21-25).

ISSUES

- 1. Whether claims 1, 3, 5, 7, 8 and 32 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 3,550,280 to Palm ("Palm") and U.S. Patent No. 4,823,244 to Alaybayoglu et al. ("Alaybayoglu").
- 2. Whether claims 2 and 6 are unpatentable under 35 U.S.C. §103(a) over Palm, Alaybayoglu, and admitted prior art.
- 3. Whether claims 1, 3-5, 7, 8-11, and 32 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,207,697 to Carusillo et al. ("Carusillo") in view of Palm and Alaybayoglu.
- 4. Whether claims 2, 6, 12, and 29-31 are unpatentable under 35 U.S.C. §103(a) over Carusillo in view of Palm, Alaybayoglu, and admitted prior art.

GROUPING OF CLAIMS

As to the rejection of claims 1-4 and 32, it is Applicants' intention that solely for the purposes of this appeal, the rejected claims stand or fall together.

As to the rejection of claims 5-10, it is Applicants' intention that solely for the purposes of this appeal, the rejected claims stand or fall together.

As to the rejection of claims 11 and 12, it is Applicants' intention that solely for the purposes of this appeal, the rejected claims stand or fall together.

As to the rejection of claims 29-31, it is Applicants' intention that solely for the purposes of this appeal, the rejected claims stand or fall together.

<u>ARGUMENT</u>

The Applicants note that Applicants' intention that claim grouping 1-4 and 32, 5-10, 11 and 12, and 29-31 stand or fall separately is based, at least in part, on the following:

Claim 1 recites limitations that are not recited in claims 5, 11 or 29. More specifically, claim 1 recites first and second opposing flanges, first and second gaps, and third and fourth flanges.

Claim 5 recites a limitation that is not recited in claims 1, 11, or 29. Specifically, claim 5 recites the single use, disposable battery pack having flat end surfaces adapted for abutting engagement.

Claims 11 recites a limitation, a rotary driven drilling member, that is not recited in claims 1, 5, or 29.

Claim 29 recites a limitation, lithium/manganese dioxide batteries, not found in claims 1, 5, or 11.

Claims 1-4 and 32

The Examiner has used Palm to disclose all elements of claims 1, 3, and 32 with the exception of "a sterile package comprising a single surgical use, disposable battery pack" which the Examiner discloses using Alaybayoglu. (page 2-5, Final Office Action). Additionally, the Examiner has used Carusillo to disclose a single use battery pack (page 6, Final Office Action). As to claim 2, the Examiner additionally refers to "admitted prior art," specifically page 10 of the Applicants' specification, to disclose "chemistry based upon lithium/manganese oxide." As to claim 4, the Examiner has used Carusillo to disclose a surgical rotary drilling instrument. As detailed below, the Applicants believe that the Examiner has improperly applied the combination of references to claims 1-4 and 32, cited nonanalagous art to establish obviousness, and improperly combined references.

A. Nonanalagous Art Cannot Be Used to Establish Obviousness

The Palm patent is the primary prior art reference that the Examiner uses in his rejections. As discussed in greater detail in the sections below, the combination of Palm and the remaining cited references are deficient for many different reasons. This deficiency is rooted, at least in part, in the fact that Palm is nonanalogous prior art and does not relate to the invention being claimed. Specifically, Palm relates to "electric hair clippers for home or professional use in cutting human hair" (column 1, lines 23-25). Thus, there is no motivation for Palm to provide or otherwise engage with a "sterile package" as required in claims 1-4 and 32.

35 U.S.C. §103 requires that obviousness be determined on the basis of whether at the time the invention was made a person of ordinary skill in the art to which the subject matter pertains would have found the claimed invention as a whole obvious. Although one of ordinary skill in the art is presumed to be aware of all prior art in the field to which the invention pertains, he is not presumed to be aware of prior art outside that field and the field of the problem to be solved, *i.e.*, nonanalogous art.

Accordingly, the Federal Circuit has described a two-part test for determining whether prior art is analogous. First, a reference is analogous if it is from the same field of endeavor as

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the invention. If a reference is outside of the inventor's field of endeavor, it may still be analogous if it is reasonably pertinent to the particular problem with which the inventor is involved. State Contracting and Eng'g Corp. v. Condotte Am. Inc., 68 USPQ2d 1481, 1489 (Fed. Cir. 2003). Here, the inventor's field of endeavor is instruments used in surgery; in Palm, the field of endeavor is instruments used in hair styling. Since hair styling is clearly outside the field of any surgery, the cited references are from nonanalogous art. Additionally, hair clippers are in no way reasonably pertinent to the problem addressed in the Applicants' disclosure, that of improved surgical instrumentation, since hair clippers are an unsuitable surgical tool. Thus, for this independent reason alone, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claims 1-4 and 32 under 35 U.S.C. §103 should be withdrawn.

Additionally, the Alaybayoglu patent is related to light sources for medical applications (column 1, lines 4-29), and is also deemed to be outside the inventor's field of endeavor.

Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness clearly cannot be met. In addition and as discussed in greater detail below, the use of the nonanalogous Palm patent suffers additional deficiencies which, for reasons of their own, also prevent supporting a *prima facie* case of obviousness.

B. Combination Fails to Teach or Suggest All Claim Elements

As the PTO recognizes in M.P.E.P. §2143, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." The Applicants hereby assert that the combination of Palm and Alaybayoglu fail to render obvious independent claim 1 because these references do not teach all limitations of the claims. Specifically, the combination of Palm and Alaybayoglu fails to teach:

- "a handpiece having a tool supporting end, and a battery receiving end;"
- "first and second opposing flanges substantially perpendicular to and opposing a longitudinal axis of the handpiece and separated by first and second gaps of substantially different widths opposing the longitudinal axis;"

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- "third and fourth flanges opposing the handpiece longitudinal axis, substantially parallel to and slidably engaged with the first and second opposing flanges, and configured to pass through a corresponding one of the first and second gaps in a single, predetermined relative position;" and
- "engagement of each of the third and fourth flanges with a corresponding one of the first and second flanges."

First, the combination of Palm and Alaybayoglu fails to teach a *handpiece* having a tool supporting end and a battery receiving end. Palm states that, "the most rearward portion 23a of the housing 23 is tapered or contoured. . . to provide a handle section which may easily be held in one hand by the operator." Housing 23 in Fig. 1 corresponds to housing 123 in Fig. 10 which the Examiner has identified as a battery pack (page 3, Final Office Action). Thus, in Palm, the housing 23 with handpiece 23a does not have a tool supporting end or a battery receiving end, but rather *is* the battery pack itself. Alaybayoglu fails to remedy this deficiency in Palm.

Second, the combination of Palm and Alaybayoglu fails to teach first and second opposing flanges substantially perpendicular to and opposing a longitudinal axis of the handpiece and separated by first and second gaps of substantially different widths opposing the longitudinal axis. The Examiner states that the first and second flanges are the "outer and most proximal rim of housing 21" in Palm and correctly observes that "the outer rim of housing 21 appears to be one monolithic piece" (page 3, Final Office Action). Because the outer rim is a monolithic piece, Palm does not teach first and second flanges separated by first and second gaps, and certainly does not teach first and second gaps of substantially different widths. Alaybayoglu fails to remedy these deficiencies in Palm.

Third, the combination of Palm and Alaybayoglu fails to teach third and fourth flanges opposing the handpiece longitudinal axis, substantially parallel to and slidably engaged with the first and second opposing flanges, and configured to pass through a corresponding one of the first and second gaps in a single, predetermined relative position. The Examiner states that the third and fourth flanges are element 126 of Fig. 10 or elements 31 and 32 of Fig. 2 of Palm (page 3, Final Office Action). These elements of Palm, however, do not appear to be substantially

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parallel to and slidably engaged with the first and second opposing flanges. Further, they are not configured to pass through the first and second gaps which, as described above, are absent from the Palm disclosure. Alaybayoglu fails to remedy these deficiencies in Palm.

Fourth, the combination of Palm and Alaybayoglu fails to teach engagement of each of the third and fourth flanges with a corresponding one of the first and second flanges. Because, as described above, Palm fails to teach first and second flanges, it further fails to teach the engagement of these flanges with the third and fourth flanges. Alaybayoglu fails to remedy these deficiencies in Palm.

Thus, for at least the above cited reasons, the combination of Palm and Alaybayoglu does not render obvious claim 1. Furthermore, Carusillo does not remedy the deficiencies of these references. Claims 2-4 and 32 depend from and further limit claim 1 and thus are also not rendered obvious by the combination of Palm, Alaybayoglu, and Carusillo.

Additionally, regarding claim 2, the Examiner correctly recognizes that the combination of Palm, Alaybayoglu, and Carusillo fails to teach "the battery pack has chemistry based upon lithium/manganese dioxide" and has cited the Applicants' own specification as evidence of obviousness (page 5 and 7, Final Office Action). The Federal Circuit, in describing the proper analysis for obviousness, has expressly stated that, "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." Thus, use of the Applicants' own specification as evidence to provide the limitation of lithium/manganese dioxide batteries is improper and based upon impermissible hindsight. For this additional reason, claim 2 is not rendered obvious.

Further, regarding claim 3, the Examiner has cited the fixed comb 62 and the reciprocating cutter 63 of Palm as being a surgical tool configured for performing a cutting operation on live human bone or hard tissue as recited in claim 3. The Applicants emphatically disagree. Comb 62 and reciprocating cutter 63 are components of the hair clipper described in Palm which specifically states that the clippers are for "home or professional use in cutting human hair" (Column 1, lines 23-25) and nowhere suggests the desirability or even the possibility of using the clippers for cutting live human bone or hard tissue. Examiner has cited

no reference describing such bone-cutting hair clippers. For this additional reason, claim 3 is not rendered obvious.

C. Combination of the References Improper

Another compelling reason why the Palm, Alaybayoglu, and Carusillo patents cannot be applied to reject claim 1 under 35 U.S.C. § 103 is that the combination of the references is improper. § 2142 of the MPEP also provides:

...the Examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made.....Knowledge of applicant's disclosure must be put aside [and] impermissible hindsight must be avoided."

Here, neither Palm, Alaybayoglu, Carusillo, nor the combination teaches, or even suggests, the desirability of the combination since neither teaches:

- a handpiece having a tool supporting end, and a battery receiving end;
- a handpiece receiving end having "... first and second opposing flanges substantially perpendicular to and opposing a longitudinal axis of the handpiece and separated by first and second gaps of substantially different width opposing the longitudinal axis ...,"
- a disposable battery pack attachment end having "... third and fourth flanges
 opposing the handpiece longitudinal axis, substantially parallel to and slidably
 engaged with the first and second opposing flanges, and configured to pass
 through a corresponding one of the first and second gaps in a single,
 predetermined relative position ...," and
- two sets of contacts "... adapted to become lockingly and conductively interengaged upon engagement of each of the third and fourth flanges with a

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corresponding one of the first and second flanges in response to rotation of [a] battery pack relative to the handpiece ..."

as is claimed in claim 1.

Thus, it is clear that none of the cited references provide any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

In this context, the MPEP further provides at § 2143.01:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case it is clear that the Examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to claim 1. Palm is entirely nonanalagous to the fields of the other cited art, light sources for medical equipment and surgical handpieces. In light of the extreme degree to which Palm, Alaybayoglu, and Carusillo are non-analogous art from clearly disparate technological fields, the fact that neither reference provides any showing, suggestion, incentive, or motivation for combination is merely logical. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met.

Claims 2-4 and 32 depend from and further limit independent claim 1. Therefore, any combination of Palm, Alaybayoglu, and Carusillo is also improper to support a rejection of claims 2-4 under 35 U.S.C. §103.

Claims 5-10

The Examiner has used Palm to disclose all elements of claims 5, 7, and 8 with the exception of "a sterile package comprising a single surgical use, disposable battery pack" which the Examiner discloses using Alaybayoglu. (page 2-5, Final Office Action). Additionally, the Examiner has used Carusillo to disclose a single use battery pack. As to claim 6, the Examiner additionally refers to "admitted prior art," specifically page 10 of the Applicants' specification, to disclose "chemistry based upon lithium/manganese oxide." As to claim 9 and 10, the Examiner has used Carusillo to disclose a surgical rotary drilling instrument comprising a separate non-circular battery pack 26 and handpiece 25. As detailed below, the Applicants believe that the Examiner has improperly applied the combination of references to claims 5-10, cited nonanalagous art to establish obviousness, and improperly combined references.

A. Nonanalagous Art Cannot Be Used to Establish Obviousness

As described above, Palm is nonanalogous art to the Applicants' invention, thus precluding any prima facie case of obviousness based on any combination including Palm and Alaybayoglu. The addition of Alaybayoglu and Carusillo does remedy this defect. Thus, for this reason alone, claims 5-10 are not rendered obvious.

B. Combination Fails to Teach or Suggest All Claim Elements

As the PTO recognizes in M.P.E.P. §2143, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." The Applicants believe that the combination of Palm and Alaybayoglu fail to render obvious independent claim 5 because these references do not teach all limitations of the claim. Specifically, the combination of Palm and Alaybayoglu fails to teach:

- "a handpiece having a battery receiving end;"
- "the central opening in the single use, disposable battery pack being adapted to insertably receive the alignment post so as to establish a mutual alignment axis of handpiece and battery pack;" and

"disposable battery pack having flat end surfaces adapted for abutting engagement"
 as taught in claim 5.

First, the combination of Palm and Alaybayoglu fails to teach a *handpiece* having a battery receiving end. Palm states that, "the most rearward portion 23a of the housing 23 is tapered or contoured. . . to provide a handle section which may easily be held in one hand by the operator." Housing 23 in Fig. 1 corresponds to housing 123 in Fig. 10 which the Examiner has identified as a battery pack (page 3, Final Office Action). Thus, in Palm, the housing 23 with handpiece 23a does not have a tool supporting end or a battery receiving end, but rather *is* the battery pack itself. Alaybayoglu fails to remedy this deficiency in Palm.

Second, the combination of Palm and Alaybayoglu fails to teach a central opening in the battery pack adapted to insertably receive the alignment post so as to establish a mutual alignment axis of handpiece and battery pack. The Examiner has stated that the battery pack 123 of Palm comprises a central opening through which the alignment post is positioned, but notably does not specify the central opening or alignment post in the drawings. Fig. 10 of Palm, in which battery pack 123 appears, clearly shows no alignment post positioned through a central opening. Fig. 3 of Palm, which depicts a corded power pack, and the related text describe an armature shaft 29 and a center opening 28. As shown in Fig. 3, the instrument is assembled without armature shaft 29 insertably received by the center opening 28 and thus the two pieces are not used to establish mutual alignment of the instrument components. As described in Palm, the center opening 28 permits limited axial movement of the motor armature (col. 4, lines 72-74) and thus is not used for alignment of the instrument components during assembly. Alaybayoglu fails to remedy this deficiency in Palm.

Third, the combination of Palm and Alaybayoglu fails to teach a disposable battery pack having flat end surfaces adapted for abutting engagement. The Examiner asserted that Palm discloses in Fig. 10 that the handpiece 16 has flat end surfaces 76 which abut against flat surfaces of element 126 of the battery pack. (page 3, Final Office Action). However, the embodiment to which the Examiner refers includes rechargeable batteries that are rechargeable by placing the entire clipper unit in a charging stand 141. (Col. 11, lines 57-75). Thus, one skilled in the art

would not look to this embodiment for motivation or suggestion (or find such motivation or suggestion therein) of a detachable battery pack, because the battery pack of this embodiment is permanently affixed and rechargeable without removal. Moreover, the flat end surfaces 76 to which the Examiner refers are not flat end surfaces. Furthermore, what is actually referred to in Palm as a "cover 76" does not have external-facing surfaces for abutting with flat end surfaces of the opposing housing unit 16. Quite the contrary, the abutting surfaces to which the Examiner refers (cover 76 and cover 126) are both located internal to the permanently attached rear housing 123. Thus, not only are the surfaces to which the Examiner refers not flat end surfaces, they are also not abutting surfaces of separate housing units.

Thus, for at least the above cited reasons, the combination of Palm and Alaybayoglu does not render claim 5 obvious. Carusillo does not remedy the deficiencies of these references. Claims 6-10 depend from and further limit claim 5 and thus are not rendered obvious by the combination of Palm, Alaybayoglu, and Carusillo.

Additionally, regarding claim 6, the Examiner correctly recognizes that the combination of Palm, Alaybayoglu, and Carusillo fail to teach "the battery pack has chemistry based upon lithium/manganese dioxide" and has cited the Applicants' own specification as evidence of obviousness (page 5 and 7, Final Office Action). As described above for claim 2, use of the Applicants' own specification as evidence to provide the limitation of lithium/manganese dioxide batteries is improper and based upon impermissible hindsight. For this additional reason, claim 6 is not rendered obvious.

C. Combination of the References Improper

Still another reason why the Palm, Alaybayoglu, and Carusillo references cannot be applied to reject claim 5 under 35 U.S. C. §103 is that the combination of the references is improprer. Here, neither Palm, Alaybayoglu, Carusillo, nor the combination teaches:

• "a handpiece having a battery receiving end;"

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- "the central opening in the single use, disposable battery pack being adapted to insertably receive the alignment post so as to establish a mutual alignment axis of handpiece and battery pack;" and
- "disposable battery pack having flat end surfaces adapted for abutting engagement" as is claimed in claim 5.

Thus, it is clear that none of the cited references provide any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

As described above, it is clear that the Examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to independent claim 5. Palm is entirely nonanalagous to the fields of the other cited art, light sources for medical equipment and surgical handpieces. In light of the extreme degree to which Palm, Alaybayoglu, and Carusillo are non-analogous art from clearly disparate technological fields, the fact that neither reference provides any showing, suggestion, incentive, or motivation for combination is merely logical. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met.

Claims 6-10 depend from and further limit independent claim 5. Therefore, any combination of Palm, Alaybayoglu, and Carusillo also fails to support a rejection of claims 6-10 under 35 U.S.C. §103.

Claims 11 and 12

The Examiner has used Palm, Alaybayoglu, and Carusillo to disclose all elements of claims 11 and 12 (pages 6-7, Final Office Action). As detailed below, the Applicants believe that the Examiner has improperly applied the combination of references to claims 11 and 12, cited nonanalagous art to establish obviousness, and improperly combined references.

A. Nonanalagous Art Cannot Be Used to Establish Obviousness

As described above, Palm is nonanalogous art to the Applicants' invention, thus precluding any prima facie case of obviousness based on any combination including Palm and Alaybayoglu. The addition of Alaybayoglu and Carusillo does remedy this defect. Thus, for this reason alone, claims 11 and 12 are not rendered obvious.

B. Combination Fails to Teach or Suggest All Claim Elements

As the PTO recognizes in M.P.E.P. §2143, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." The Applicants believe that the combination of Palm and Alaybayoglu fail to render obvious independent claim 11 because these references do not teach all limitations of the claims. Specifically, the combination of Palm, Alaybayoglu, and Carusillo fails to teach:

- "a handpiece having . . . a tool supporting end and a battery receiving end" and
- a "central opening in the disposable battery being adapted to receive the alignment post of the handpiece in a partially inserted position so as to establish a pre-attachment alignment thereof"

First, the combination of Palm and Alaybayoglu fails to teach a *handpiece* having tool supporting and battery receiving ends. Palm states that, "the most rearward portion 23a of the housing 23 is tapered or contoured. . . to provide a handle section which may easily be held in one hand by the operator." Thus, in Palm, the handpiece 23a does not have a battery receiving end or a tool supporting end. Alaybayoglu fails to remedy this deficiency in Palm.

Second, the combination of Palm and Alaybayoglu fails to teach a central opening in the battery pack adapted to insertably receive the alignment post in a partially inserted position so as to establish a pre-attachment alignment thereof. As described above, the Palm fails to teach using an alignment post and central opening for establishing a pre-attachment alignment. Alaybayoglu fails to remedy this deficiency in Palm.

Thus, for at least the above cited reasons, the combination of Palm and Alaybayoglu does not render claim 11 obvious. Carusillo does not remedy the deficiencies of these references.

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Claim 12 depends from and further limits claim 11 and thus is not rendered obvious by the combination of Palm, Alaybayoglu, and Carusillo.

Additionally, regarding claim 12, the Examiner correctly recognizes that the combination of Palm, Alaybayoglu, and Carusillo fail to teach "the battery pack has chemistry based upon lithium/manganese dioxide" and has cited the Applicants' own specification as evidence of obviousness (page 5 and 7, Final Office Action). As described above for claim 2, use of the Applicants' own specification as evidence to provide the limitation of lithium/manganese dioxide batteries is improper and based upon impermissible hindsight. For this additional reason, claim 12 is not rendered obvious.

C. Combination of the References Improper

Still another reason why the Palm, Alaybayoglu, and Carusillo references cannot be applied to reject claim 11 under 35 U.S. C. §103 is that the combination of the references is improprer. Here, neither Palm, Alaybayoglu, Carusillo, nor the combination teaches:

- "a handpiece having . . . a tool supporting end and a battery receiving end" and
- a "central opening in the disposable battery being adapted to receive the alignment post of the handpiece in a partially inserted position so as to establish a preattachment alignment thereof"

as is claimed in claim 11.

Thus, it is clear that none of the cited references provide any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

As described above, it is clear that the Examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to independent claim 11. Palm is entirely nonanalagous to the fields of the other cited art, light sources for medical equipment and surgical handpieces. In light of the extreme degree to which Palm, Alaybayoglu, and Carusillo are non-

analogous art from clearly disparate technological fields, the fact that neither reference provides any showing, suggestion, incentive, or motivation for combination is merely logical. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met.

Claim 12 depends from and further limits independent claim 11. Therefore, any combination of Palm, Alaybayoglu, and Carusillo also fails to support a rejection of claim 12 under 35 U.S.C. §103.

Claims 29-31

The Examiner has used Palm, Alaybayoglu, Carusillo and purportedly admitted art to disclose all elements of claims 29-31 (page 7, Final Office Action). As detailed below, the Applicants believe that the Examiner has improperly applied the combination of references to claims 29-31, cited nonanalagous art to establish obviousness, and improperly combined references.

A. Nonanalagous Art Cannot Be Used to Establish Obviousness

As described above, Palm is nonanalogous art to the Applicants' invention, thus precluding any prima facie case of obviousness based on any combination including Palm and Alaybayoglu. The addition of Alaybayoglu and Carusillo does remedy this defect. Thus, for this reason alone, claims 29-31 are not rendered obvious.

B. Combination Fails to Teach or Suggest All Claim Elements

As the PTO recognizes in M.P.E.P. §2143, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." The Applicants believe that the combination of Palm and Alaybayoglu fail to render obvious independent claim 29 because these references do not teach all limitations of the claim. Specifically, the combination of Palm, Alaybayoglu, and Carusillo fails to teach:

• "a handpiece including a first end supporting a rotary driven tool. . . and a second end having an alignment post;"

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- "lithium/manganese dioxide batteries;" and
- "the attachment end opening is configured to receive the handpiece alignment post so as to establish a mutual alignment axis"

as claimed in claim 29.

First, the combination of Palm and Alaybayoglu fails to teach a *handpiece* a first end supporting a tool and a second end having an alignment post. Palm states that, "the most rearward portion 23a of the housing 23 is tapered or contoured. . . to provide a handle section which may easily be held in one hand by the operator." Housing 23 in Fig. 1 corresponds to housing 123 in Fig. 10 which the Examiner has identified as a battery pack (page 3, Final Office Action). Thus, in Palm, the housing 23 with handpiece 23a does not have a tool supporting end or a battery receiving end, but rather *is* the battery pack itself. Alaybayoglu fails to remedy this deficiency in Palm.

Second, the Examiner correctly recognizes that the combination of Palm, Alaybayoglu, and Carusillo fails to teach "the battery pack has chemistry based upon lithium/manganese dioxide" and has cited the Applicants' own specification as evidence of obviousness (page 5 and 7, Final Office Action). As described above for claim 2, use of the Applicants' own specification as evidence to provide the limitation of lithium/manganese dioxide batteries is improper and based upon impermissible hindsight. For this additional reason, claim 29 is not rendered obvious.

Third, the combination of Palm and Alaybayoglu fails to teach the attachment end opening is configured to receive the handpiece alignment post so as to establish a mutual alignment axis. As described above, Palm fails to teach using an alignment post and opening for establishing a mutual alignment axis. Alaybayoglu fails to remedy this deficiency in Palm.

Thus, for at least the above cited reasons, the combination of Palm and Alaybayoglu does not render claim 29 obvious. Carusillo does not remedy the deficiencies of these references. Claims 30 and 31 depend from and further limit claim 29 and thus are not rendered obvious by the combination of Palm, Alaybayoglu, and Carusillo.

C. Combination of the References Improper

Still another reason why the Palm, Alaybayoglu, and Carusillo references cannot be applied to reject claim 29 under 35 U.S. C. §103 is that the combination of the references is improprer. Here, neither Palm, Alaybayoglu, Carusillo, nor the combination teaches:

- "a handpiece including a first end supporting a rotary driven tool. . . and a second end having an alignment post;"
- "lithium/manganese dioxide batteries;" and
- "the attachment end opening is configured to receive the handpiece alignment post so as to establish a mutual alignment axis"

as claimed in claim 29.

Thus, it is clear that none of the cited references provide any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

As described above, it is clear that the Examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to independent claim 29. Palm is entirely nonanalagous to the fields of the other cited art, light sources for medical equipment and surgical handpieces. In light of the extreme degree to which Palm, Alaybayoglu, and Carusillo are non-analogous art from clearly disparate technological fields, the fact that neither reference provides any showing, suggestion, incentive, or motivation for combination is merely logical. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met.

Claims 30 and 31 depend from and further limit independent claim 29. Therefore, any combination of Palm, Alaybayoglu, and Carusillo also fails to support a rejection of claims 30 and 31 under 35 U.S.C. §103.

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CONCLUSION

Accordingly, it is respectfully submitted that the combination of the Palm, Alaybayoglu, and Carusillo does not disclose or suggest the subject matter of claims 1-12 and 29-32. Furthermore, the references include nonanalagous art which cannot be used to establish obviousness. Moreover, it is respectfully submitted that it is improper to combine the references because there is no motivation or suggestion for such combination to achieve the Applicants' claimed elements.

For all of the foregoing reasons, it is respectfully submitted that claims 1-12 and 29-32 be allowed. A prompt notice to that effect is earnestly solicited.

Respectfully submitted,

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APPENDIX A

- 1. A surgical instrument comprising:
- (a) a handpiece having a tool supporting end, and a battery receiving end, the battery receiving end having:

a first set of substantially concentrically arranged electrical contacts; and first and second opposing flanges substantially perpendicular to and opposing a longitudinal axis of the handpiece and separated by first and second gaps of substantially different widths opposing the longitudinal axis; and

(b) a sterile package comprising a single surgical use, disposable battery pack having an attachment end, the attachment end having:

a second set of substantially concentrically arranged electrical contacts; and third and fourth flanges opposing the handpiece longitudinal axis, substantially parallel to and slidably engaged with the first and second opposing flanges, and configured to pass through a corresponding one of the first and second gaps in a single, predetermined relative position;

- (c) wherein the two sets of contacts are adapted to become lockingly and conductively interengaged upon engagement of each of the third and fourth flanges with a corresponding one of the first and second flanges in response to rotation of the battery pack relative to the handpiece.
- 2. A surgical instrument as in Claim 1 wherein the battery pack has chemistry based upon lithium/manganese dioxide, the battery pack after use being disposable into non-hazardous waste.
- 3. The surgical instrument as in Claim 1 further comprising a surgical tool coupled to the tool supporting end and configured for performing a cutting operation on live human bone or hard tissue.

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- 4. The surgical instrument as in Claim 1 further comprising a surgical tool coupled to the tool supporting end and configured for performing a drilling operation on live human bone or hard tissue.
- 5. A surgical instrument for performing a cutting, shaping, or drilling operation on live human bone or hard tissue, comprising:
- (a) a handpiece having a battery receiving end with an alignment post extending therefrom and a tool supporting end for supporting a tool for performing a cutting, shaping, or drilling operation on live human bone or hard tissue; and
- (b) a sterile package containing a single use, disposable battery pack which has an attachment end with a central opening therein;
- (c) the central opening in the single use, disposable battery pack being adapted to insertably receive the alignment post so as to establish a mutual alignment axis of handpiece and battery pack;
- (d) the battery receiving end of the handpiece and the attachment end of the single use, disposable battery pack having flat end surfaces adapted for abutting engagement while yet allowing relative rotation of the battery pack relative to the handpiece;
- (e) the battery receiving end of the handpiece and the attachment end of the single use, disposable battery pack having mating sets of electrical contact elements, each set being arranged generally concentric to the mutual alignment axis; and
- (f) wherein upon the insertion of the alignment post of the handpiece into the opening of the battery pack, the sets of mating contacts are adapted to then become lockingly and conductively interengaged in response to rotation of the battery pack relative to the handpiece.
- 6. The apparatus of Claim 5 wherein the chemistry of the disposable battery pack is based upon lithium/manganese dioxide.
- 7. The apparatus of Claim 5 including means providing a spring-supported snap action whereby the sets of mating contacts become lockingly and conductively interengaged in response to rotation of the battery pack relative to the handpiece.

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- 8. (Original) The apparatus of Claim 7 wherein the spring-supported snap action means provides an audible sound indicating that the mating contacts and the battery have been correctly and securely locked in position.
- 9. The apparatus of Claim 5 wherein the battery receiving end of the handpiece, and the attachment end of the battery pack, each has a non-circular external cross-sectional configuration, the two external configurations being closely similar in both size and shape, and the rotational position of the battery pack for locking the contacts being such that the handpiece and the battery pack then provide an essentially continuous external surface which indicates to the hand of the operator that correct alignment of the contacts has been achieved.
- 10. The apparatus of Claim 9 including means providing a spring-support snap action whereby the sets of mating contacts become lockingly and conductively interengaged in response to rotation of the battery pack relative to the handpiece.
- 11. A surgical instrument for performing a surgical drilling procedure on bone or hard tissue, comprising:
- (a) a handpiece having a rotary driven drilling member supported by a tool supporting end, and a battery receiving end with an alignment post extending therefrom, the battery receiving end of the handpiece also having a set of electrical contact elements arranged in generally concentric relation to the alignment post;
- (b) a disposable battery having an attachment end with a central opening therein, and a set of mating electrical contact elements arranged in a generally circular configuration concentric to the central opening therein;
- (c) the central opening in the disposable battery being adapted to receive the alignment post of the handpiece in a partially inserted position so as to establish a pre-attachment alignment thereof;
- (d) the sets of mating contacts being adapted to come into a mutually concentric relation in response to a further insertion of the alignment post into the central opening; and

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- (e) the sets of contacts being adapted to then become lockingly and conductively interengaged upon rotation of the battery pack relative to the handpiece.
- 12. The apparatus of Claim 11 wherein the chemistry of the disposable battery is based upon lithium/manganese dioxide, and which further includes a sterile package containing the disposable battery.
 - 13-28. (Canceled)
 - 29. A surgical instrument for removing live human bone or hard tissue, comprising: a handpiece including:
 - a first end supporting a rotary driven tool configured to remove live human bone or hard tissue by rotation of a cutting member in response to rotary drive means within the handpiece; and

a second end having:

an alignment post extending therefrom and defining a handpiece longitudinal axis; and

a plurality of handpiece electrical contacts arranged concentric to the handpiece longitudinal axis; and

a sterile, disposable battery pack including:

lithium/manganese dioxide batteries; and

an attachment end configured to be secured to the handpiece second end by means of a rotating movement of the disposable battery pack relative to the handpiece, the attachment end having:

an opening therein defining a battery pack longitudinal axis; and a plurality of battery pack electrical contacts arranged concentric to the battery pack longitudinal axis; wherein

the attachment end opening is configured to receive the handpiece alignment post so as to establish a mutual alignment axis between the handpiece longitudinal axis and the battery pack longitudinal axis; and

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the pluralities of the handpiece and battery pack contacts are mating pluralities of contacts configured to be lockingly and conductively interengaged in response to the rotating movement.

- 30. The surgical instrument of Claim 29 wherein the handpiece and the disposable battery pack each have a substantially non-circular external cross-sectional configuration and provide a substantially continuous external surface when the pluralities of handpiece and battery pack contacts are lockingly and conductively interengaged.
- 31. The surgical instrument of Claim 29 wherein the handpiece second end includes first flat end surfaces and the disposable battery pack includes second flat end surfaces configured for abutting engagement with the first flat end surfaces while allowing rotation of the battery pack relative to the handpiece.
- 32. The surgical instrument as in Claim 1 further comprising a surgical tool coupled to the tool supporting end and configured for performing a shaping operation on live human bone or hard tissue.